510(k) number:	K090700
Submitter:	Meridian Bioscience: Inc.
Submitter's address:	3471 River Hills Drive Cincinnati, OH 45244
Contact:	Susan Rolih
Contact number:	(513) 271 3700
Date of preparation:	March 16, 2009

MAY 28 2009

Device name:	Immuno*Card* STAT! CAMPY
Common name:	Rapid immunochromatographic assay for *Campylobacter*
Classification name:	*Campylobacter ssp.* LQP, CFR section 866.3110
Predicate device:	K982315, ProSpecT Campylobacter EIA
Reference comparator	Bacterial culture

Description of the device:

ImmunoCard STAT! CAMPY is an immunochromatographic, rapid test for the detection of specific *Campylobacter* antigens in stool samples from patients with signs and symptoms of Campylobacteriosis. The assay is intended to be used by hospital and reference laboratories to test for bacterial colonization. It is used in conjunction with information obtained from the patient's clinical symptoms and with other tests to diagnose Campylobacter infection. The assay consists of ImmunoCard STAT! Test Devices (containing specific capture antibodies and colloidal gold-antibody conjugate detector antibodies), Immuno*Card* STAT! CAMPY Sample Diluent/Negative Control and Immuno*Card* STAT! CAMPY Positive Control.

No calibrators are used with this device.

Intended use:

Immuno*Card* STAT! CAMPY is an immunochromatographic rapid test for the qualitative detection of specific *Campylobacter* antigens in human stool. Immuno*Card* STAT! CAMPY detects *C. jejuni* and *C. coli* in human stool, where stool may be either unpreserved or preserved in Cary-Blair-based transport media. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.

Immuno*Card* STAT! CAMPY is not intended for point-of-care use. The device is intended for use in clinical hospital, reference, regional, private or state laboratory settings.

Comparison to predicate device:

Item	***ImmunoCard STAT! CAMPY***	***Predicate device ProSpecT Campylobacter***	***Predicate Device Premier CAMPY***
Manufacturer	Meridian Bioscience	Remel	Meridian Bioscience
Assay type	Lateral flow	EIA	EIA
Intended use			
· Qualitative/Quantitative	Qualitative	Qualitative	Qualitative
Screening, diagnostic or identification test	Diagnostic	Diagnostic	Diagnostic
Calibrator	No	No	No
Monitoring therapy	No	No	No
Reagents/components			
Microwells	No	Yes	Yes
Sample Diluent	Yes	Yes	Yes
Enzyme Conjugate	No	Yes	Yes
Wash Buffer	No	Yes	Yes
Substrate	No	Yes	Yes
Stop Solution	No	Yes	Yes
Positive Control	Yes	Yes	Yes
Negative Control	Yes	Yes	Yes
Test Device	Yes	No	No
Species detected			
C. jejuni	Yes	Yes	Yes
C. coli	Yes	Unk	Yes
C. lari	No	No	No
C. fetus	No	No	No
Reading method			
· Visual	Yes	Yes	Yes
Spectrophotometric	No	Yes	Yes
End point	Pos = visible pink-red line Neg = no line	Pos = yellow color Negative = colorless	Pos = definite yellow color Neg = colorless to very faint yellow
Calibrator	No	No	No

Comparison to predicate cont'd

Item	*ImmunoCard STAT! CAMPY*	*Predicate device ProSpecT Campylobacter*	*Predicate device Premier CAMPY*
Equipment	Not needed	General laboratory semiautomated washer (optional) General laboratory spectrophotometer (optional)	General laboratory semiautomated washer (optional) General laboratory spectrophotometer (optional) StatFax microplate incubator/shaker (optional)
Antibody sources			
Capture	Mouse monoclonal	Rabbit polyclonal	Mouse monoclonal
Detector	Mouse monoclonal	Rabbit polyclonal	Mouse monoclonal
Sample Types			
Human stool (direct)	Yes	Yes	Yes
Broth culture	No	Yes	No
Endpoint determinations			
Visible?	Yes – pink-red line	Yes – yellow color	Yes – yellow color
Positive (dual wavelength)	N/A	Yes ≥ 0.140	Yes ≥ 0.100
Negative (dual wavelength)	N/A	Yes < 0.100	Yes < 0.100
Indeterminant (dual wavelength)	N/A	Yes 0.100 to 0.139	None

Performance comparison – Nonclinical tests

Interference testing

Selected drugs and other nonmicrobial substances that might be present in stool samples from healthy persons or patients with signs and symptoms of gastroenteritis were added to three positive and three negative samples. The samples were inoculated with *C. jejuni* near the assay's limit of detection (LoD). The final concentrations of the substances in the samples were as follows: Barium sulfate (5 mg/mL); fecal fat (equivalent to 2.65 mg stearic plus 1.3 mg palmitic acids per mL), hemoglobin (as methhemoglobin) (3.2 mg/mL), Imodium AD® (0.00667 mg/mL), Kaopectate® (0.87 mg/mL), mucin (3.33 mg/mL), Mylanta® (4.2 mg/mL), Pepto-Bismol® (0.87 mg/mL), Prilosec® (0.5 mg/mL), Tagamet® (0.5 mg/mL), TUMS® (0.5 mg/mL), urine (5% V/V), and whole blood (5% v/v). The spiked samples were tested in parallel with an unspiked dilution control for reference. None of the potentially interfering substances met the criteria for an interferent.

Crossreactivity study

Microorganisms that were present as normal intestinal flora or associated with gastroenteritis were evaluated as to their effects on assay performance. Fungus and bacteria were tested at final concentrations in human stool of 1.1×10^8 CFU/mL. Viruses were tested at final concentrations of 1.3×10^4 to 3.1×10^6 $TCID_{50}$/mL. None of the following organisms in stool reacted with Immuno*Card* STAT! CAMPY:

Aeromonas hydrophila, Bacteroides fragilis, Campylobacter fetus, Candida albicans, Citrobacter freundi, Clostridium difficile, C. perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, E. coli O157:H7, *E. fergusonii, E. hermannii, Helicobacter pylori, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Proteus vulgaris, Pseudomonas aeruginosa, P. fluorescens,* Salmonella Groups B-E, *Serratia marcescens, Shigella boydii, S. flexneri, S. sonnei, Staphylococcus aureus, S. epidermidis, Vibrio parahaemolyticus, Yersinia enterocolitica,* Adenovirus Types 40 and 41, Coxsackievirus, Echovirus, Rotavirus

Performance comparison – Clinical tests

The performance of Immuno*Card* STAT! CAMPY was established in clinical trials using bacterial culture as the reference comparator method. Three independent test sites located in the Midwestern and Southeastern regions of the United States tested a total of 421 qualified patient samples. Of these, 189 were retrospective frozen samples. Forty-nine percent were collected in a Cary Blair-based transport and preservative medium. The remaining samples were tested in the unpreserved state. Samples were collected from males (44%) and females (52%). In the case of 4% of the patients, the gender was not known. The age groups of the patients ranged from less than one month of age to 95 years. No differences in test performance were observed based on patient age or gender. The following tables show the assay performance by clinical site, patient age and sample type.

Table 1. Performance characteristics by clinical site

	Positive Samples			Negative Samples		
Site	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	17/17	100%	81.6-100%	92/95	96.8%	91.1-98.9%
Site 2	18/19	94.7%	75.4-99.1%	130/135	96.3%	91.6-98.4%
Site 3	17/17	100%	81.6-100%	131/138	94.9%	89.9-97.5%
Combined Sites	52/53	98.1%	90.1-99.7%	353/368	95.9%	93.4-97.5%

Table 2 – Performance characteristics by patient age

	Positive Samples			Negative Samples		
Patient Age	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Birth to 1 month	0/0	N/A	N/A	1/1	100%	20.7-100%
> 1 month to 2 years	2/2	100%	34.2-100%	66/68	97.1%	89.9-99.2%
> 2 years to 12 years	5/5	100%	56.6-100%	88/93	94.6%	88.0-97.7%
> 12 years to 21 years	1/1	100%	20.7-100%	40/42	95.2%	84.2-98.7%
> 21 years	27/28	96.4%	82.3-99.4%	158/164	96.3%	92.2-98.3%
Not Defined	17/17	100%	81.6-100%	0/0	N/A	N/A

Table 3 – Performance characteristics by sample type (preserved vs unpreserved)

	Positive Samples			Negative Samples		
Specimen Type Preserved	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	12/12	100%	75.8-100%	92/95	96.8%	91.1-98.9%
Site 2	13/14	92.9%	68.5-98.7%	61/66	92.4%	83.5-96.7%
Site 3	17/17	100%	81.6-100%	1/1	100%	20.7-100%
Specimen Type Unpreserved	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	5/5	100%	56.6-100%	0/0	N/A	N/A
Site 2	5/5	100%	56.6-100%	69/69	100%	94.7-100%
Site 3	0/0	N/A	N/A	130/137	94.9%	89.8-97.5%

Table 4 – Performance characteristics of fresh and frozen samples

	Positive Samples			Negative Samples		
Specimen Type Fresh	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	0/0	N/A	N/A	91/94	96.8%	91.0-98.9%
Site 2	2/3	66.7%	20.8-93.9%	130/135	96.3%	91.6-98.4%
Site 3	0/0	N/A	N/A	0/0	N/A	N/A
Total Fresh	2/3	66.7%	20.8-93.9%	221/229	96.5%	93.3-98.2%
Specimen Type Frozen	**ICS/ Culture**	**Sensitivity %**	**95% CI**	**ICS/ Culture**	**Specificity %**	**95% CI**
Site 1	17/17	100%	81.6-100%	1/1	100%	20.7-100%
Site 2	16/16	100%	80.6-100%	0/0	N/A	N/A
Site 3	17/17	100%	81.6-100%	131/138	94.9%	89.9-97.5%
Total Frozen	50/50	100%	92.9-100%	132/139	95.0%	90.0-97.5%

Analytical sensitivity

The analytical sensitivity of this assay for *C. jejuni* and *C. coli* was based on 45 tests for each measurand and with a stated probability (eg, 95%) of obtaining positive responses at the following levels of the measurands: *C. jejuni* 1.2×10^7 cells/mL; *C. coli* 3.0×10^7 cells/mL.

Reproducibility

Assay precision, intra-assay variability and inter-assay variability were assessed with a reference panel prepared from moderate positive (n = 2), negative (n = 2), high negative (n = 3) and low positive (n = 3) samples. High negative, low positive and moderate positive samples were prepared by inoculating negative stool matrix with known quantities of *C. jejuni.* In the case of low positive and high negative samples, the inoculum was added at concentrations that were at, or just below, the assay LoD. Aliquots of each panel were tested for five days, twice each day at three different test sites (Sites A, B and C). At least two technologists performed testing at each site.

As can be seen in Tables 5 – 9, the expected results were obtained 99.7% of the time.

Table 5. Site 1 data

Sample ID	Sample Qual. Result	Site 1 data generated with kit lot 751530.001									
		Day 1 Run 1 DH	Day 1 Run 2 AML	Day 2 Run 1 DH	Day 2 Run 2 AML	Day 3 Run 1 DH	Day 3 Run 2 AML	Day 4 Run 1 DH	Day 4 Run 2 AML	Day 5 Run 1 DH	Day 5 Run 2 AML
Positive Control	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: DH etc = initials of person performing the test, Pos = positive, Neg = negative

Table 6. Site 2 data

Sample ID	Sample Qual. Result	Site 2 data generated with lot 751530.001									
		Day 1 Run 1 DM	Day 1 Run 2 JM	Day 2 Run 1 DM	Day 2 Run 2 JM	Day 3 Run 1 DM	Day 3 Run 2 JM	Day 4 Run 1 DM	Day 4 Run 2 JM	Day 5 Run 1 DM	Day 5 Run 2 JM
Positive Control	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Neg	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	83.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: DH etc = initials of person performing the test, Pos = positive, Neg = negative

Table 7. Site 3 data

Sample ID	Sample Qual. Result	Site 3 data generated with lot 751530.001									
		Day 1 Run 1 KC	Day 1 Run 2 KMA	Day 2 Run 1 KC	Day 2 Run 2 KMA	Day 3 Run 1 KC	Day 3 Run 2 KMA	Day 4 Run 1 KC	Day 4 Run 2 KMA	Day 5 Run 1 KC	Day 5 Run 2 KMA
Positive Control	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Negative Control	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Moderate Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Moderate Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 1	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 2		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
Low Positive 3		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
High Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
High Negative 3		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 1	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Low Negative 2		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: DH etc = initials of person performing the test, Pos = positive, Neg = negative

Conclusions

ImmunoCard STAT! CAMPY:

1. Can be used to detect *C. jejuni and C. coli.* in human stool.
2. The test is diagnostic for the presence of *C. jejuni* and *C. coli.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 28 2009

Ms. Susan Rolih
Senior Vice President, RA/QA
Meridian Bioscience, Inc
3471 River Hills Drive
Cincinnati, OH 45244

Re: k090700
Trade/Device Name: ImmunoCard STAT! CAMPY
Regulation Number: 21 CFR § 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LQP
Dated: April 15th, 2009
Received: May 13th, 2009

Dear Ms. Rolih:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090700

Device Name: Immuno*Card* STAT! CAMPY

Indication For Use:

Immuno*Card* STAT! CAMPY is an immunochromatographic rapid test for the qualitative detection of specific *Campylobacter* antigens in human stool. Immuno*Card* STAT! CAMPY detects *C. jejuni* and *C. coli* in human stool, where stool may be either unpreserved or preserved in Cary-Blair-based transport media. Test results are to be used in conjunction with information available from the patient's clinical evaluation and other diagnostic procedures.

Immuno*Card* STAT! CAMPY is not intended for point-of-care use. The device is intended for use in hospital, reference, regional, private or state laboratory settings.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090700